

## § 522.1680

*albus*, *Brucella bronchiseptica*, *Streptococcus* spp.

(2) The drug is administered intramuscularly at a recommended daily dosage to dogs at 5 milligrams per pound of body weight administered in divided doses at 6 to 12 hour intervals. Therapy should be continued for at least 24 hours after all symptoms have subsided.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 30615, July 5, 1983]

### § 522.1680 Oxytocin injection.

(a) *Specifications*. Each milliliter of oxytocin injection contains 20 U.S.P. units of oxytocin.

(b) *Sponsors*. See Nos. 000010, 000856, 000864, 059130, 058639, and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use*<sup>1</sup>—(1) *Amount*—(i) *Obstetrical*. Administer drug intravenously, intramuscularly, or subcutaneously under aseptic conditions as indicated. The following dosages are recommended and may be repeated as conditions require:

	ml	U.S.P. units
Cats .....	0.25 to 0.5 .....	5 to 10.
Dogs .....	0.25 to 1.5 .....	5 to 30.
Ewes, Sows .....	1.5 to 2.5 .....	30 to 50.
Cows, Horses .....	5.0 .....	100.

(ii) *Milk letdown*. Intravenous administration is desirable. The following dosage is recommended and may be repeated as conditions require:

	ml	U.S.P. units
Cows .....	0.5 to 1.0 .....	10 to 20.
Sows .....	0.25 to 1.0 .....	5 to 20.

(2) *Indications for use*. Oxytocin may be used as a uterine contractor to precipitate and accelerate normal parturition and postpartum evacuation of uterine debris. In surgery it may be used postoperatively following cesarean section to facilitate involution and

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bio-equivalency and safety information.

## 21 CFR Ch. I (4–1–02 Edition)

resistance to the large inflow of blood. It will contract smooth muscle cells of the mammary gland for milk letdown if the udder is in proper physiological state.

(3) *Limitations*. Do not use in dystocia due to abnormal presentation of fetus until correction is accomplished. For prepartum usage, full relaxation of the cervix should be accomplished either naturally or by administration of estrogen prior to oxytocin therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 63097, Nov. 2, 1979; 45 FR 1019, Jan. 4, 1980, as amended at 52 FR 18691, May 19, 1987; 52 FR 25212, July 6, 1987; 52 FR 36023, Sept. 25, 1987; 53 FR 32610, Aug. 26, 1988; 53 FR 40728, Oct. 18, 1988; 54 FR 41442, Oct. 10, 1989; 55 FR 8462, Mar. 8, 1990; 56 FR 14642, Apr. 11, 1991; 56 FR 16002, Apr. 19, 1991; 59 FR 31139, June 17, 1994; 62 FR 35076, June 30, 1997; 62 FR 38906, July 21, 1997; 65 FR 45877, July 26, 2000; 66 FR 22117, May 3, 2001]

### § 522.1696 Penicillin G procaine implantation and injectable dosage forms.

#### § 522.1696a Penicillin G benzathine and penicillin G procaine sterile suspension.

(a) *Specifications*. Each milliliter of aqueous suspension contains penicillin G benzathine and penicillin G procaine, each equivalent to 150,000 units of penicillin G.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for the conditions of use in paragraph (d) of this section as follows:

(1) Nos. 000008, 000856, 000864, 010515, and 049185 for use as in paragraph (d)(1) of this section.

(2) Nos. 000856 and 049185 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(2)(iii) of this section.

(3) Nos. 000864, 010515, and 059130 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(B), and (d)(2)(iii) of this section.

(c) *Related tolerances*. See § 556.510 of this chapter.

(d) *Conditions of use*—(1) *Horses, dogs, and beef cattle*—(i) *Amount*—(A) *Beef cattle*. 2 milliliters per 150 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.